

## REMARKS

### I. Status of the Claims

Claims 1-5, 7-8, 10-21, 23-24 and 28 are pending in this application.

Claims 1, 17, 20, 23, and 24 are in independent form. Dependent claim 12 has been cancelled and the Markush group of lipid ingredients previously in claim 12 has been incorporated into the independent claims. Dependent claim 28 is a new claim reciting the presence of a cooling compound with the acidulent in the salivation region of claim 24.

### II. Rejections Under 35 U.S.C. § 103

Claims 1-5, 7-8, 10-11, 15-18, and 23-24 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. 6,231,900 B1 (hereinafter “Hanke”). Claim 19 was rejected over Hanke in view of U.S. Patent No. 6,099,880 (hereinafter “Klacik”). Claims 20-21 were rejected over Hanke in further view of NIH/National Institute of Dental and Craniofacial Research publication “Dry Mouth,” published June 1999 (hereinafter “the NIH document”). Claims 1-5, 7-8, 10-14, 17, 20 and 23-24 were rejected as allegedly being obvious over U.S. 5,284,659 (hereinafter “Cherukuri”) in view of WO 99/579427 (hereinafter “Le”).

### III. Amendments

The independent claims have been amended to incorporate the features of claim 12. As claim 12 was not rejected over Hanke, the rejection over Hanke should not apply to the present independent claims. Hanke was applied against the claims on the basis that the composition A in Hanke “reads on the instantly claimed oral comfort region comprising a lipid since Hanke teaches the use of a flavor oil in this region” (Office Action, page 4). A flavor oil (being a terpene, or containing terpenes) is not “selected

from the group consisting of partially hydrogenated palm kernel oil, medium chain triglycerides, coconut oil, anhydrous milk fat, cocoa butter, corn oil, palm oil, soybean oil, sunflower oil, canola oil and mixtures thereof" as required by the present independent claims. Moreover, as noted in the previously filed Declaration of Kevin Stanton, one of ordinary skill would not consider a flavor oil an oral comfort ingredient as that would be inconsistent with the materials safety information for that ingredient.

Claims 15 and 16 recite the presence of cooling compound with the acidulent in the salivation region. These claims were not rejected over Cherukuri in view of Le. Presumably, these claims are now allowable over the references. Likewise, new claim 28, which also recites the presence of cooling compound with the acidulent in the salivation region, should be allowable for the same reasons.

IV. None of the Claims Are Obvious In View of Hanke

It is believed that the rejection over Hanke is overcome by the foregoing amendment, in that all of the independent claims recite a Markush group of lipids that does not include flavor oils.

Moreover, there is no motivation taught in Hanke to make a confectionery product as set forth in the present claims. Hanke teaches a confectionery product for soothing sore throat and relief of symptoms associated with cough and cold. Hanke teaches that cooling compounds had been found to have a negative impact on flavors (Hanke, col. 1, lines 38-45), and to address the problem, the product disclosed in Hanke provides a flavor region and a cooling region which are discrete from each other and adapted to provide a different release profile for the flavor and cooling compounds, respectively (Hanke, col. 2, lines 29-31). In the embodiments that are taught, the flavor

releases earlier. Note that Hanke does not say, or imply, that the negative impact of cooling compounds on flavors would also be addressed by having the cooling compound release first, and that would appear to defy common sense.

Notwithstanding that the “preferred” flavor profile is to have more acidulant in the flavor-containing region (Hanke, col. 8, lines 18-20), the Examiner argues that “it would have been *prima facie* obvious to utilize a higher concentration of acidulant in the coolant composition if one desired to have the coolant release earlier than the flavor composition” (Office Action, page 5).

This is an insufficient motivation statement for an obviousness rejection. To reach the result one is required to start with the “desire to have the coolant release earlier than the flavor composition.” That desire is not found in the references, would not occur to one of ordinary skill in the art, and in fact is pure hindsight.

*In re Susi* is not relevant here. In that case, the reference taught two different classes of compounds used for the same purpose, teaching one as more preferred than the other. The CCPA said that the teaching of the more preferred embodiment did not ‘teach away’ from the less preferred. The present case presents a different scenario, in that the reference does not provide a motivation for the opposite release profile to what is taught in the reference Examples.

#### V. Rejections Over Hanke In View Of Secondary References

Recognizing that Hanke does not teach a method for treating xerostomia, or dry mouth, the present Office Action now alleges that it would have been obvious to treat dry mouth with the item disclosed in Hanke, because the NIH document discloses that sucking sugarless candy may alleviate symptoms of dry mouth and because Hanke

discloses an item used to alleviate cough and cold symptoms. Neither motivation is sufficient to arrive at the claimed invention (which for example, includes sugar bases expressly recited in some of the claims).

Klacik is applied in combination with Hanke against Claim 19. Whatever the merits of Klacik with respect to the mold limitation, the secondary reference does not disclose the elements of independent Claim 17, discussed above.

VI. The Claims Are Not Obvious in View of Cherukuri and Le

Cherukuri is relied on to show a product having two phases (referred to in the reference as a “shell” and a “core”) in two separate regions. This is depicted in Fig.

6. The shell region contains breath deodorant, and the Office Action maintains that the region may contain other “bio-effecting” agents (Office Action, page 11). However, the reference does not teach an acidulant, or other agent, in that region to increase salivation.

The core region contains fat encapsulation, which in some embodiments “may be combined with a diluent, lubricant, and/or bonding agent. Such agents are well known in the art. For example, diluents may include lactose, Avicel® microcrystalline cellulose NF, or starch, talc, sorbitol, mannitol, polydextrose, calcium carbonate, Palatinit®, maltitol, xylitol, other sugar alcohols and sugar” (Cherukuri, col. 8, lines 55-65). One of ordinary skill in the art would not consider this description of the diluent to read on a “sugar or sugarless confectionery base,” as claimed.

According to the Office Action, page 15, “the examiner only relies on Le for the specific teaching of utilizing acidulents as the active agent of choice.”

The Office Action alleges that it would have been obvious to form a salivation region having a concentration of acidulant in one region on the basis that (1) a

skilled artisan would have been motivated to utilize an acidulent in Cherukuri's example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth rather than halitosis; and (2) one would have been motivated to utilize an acidulent in the shell portion to increase the rate of release of first flavor in the . . . shell portion (Office Action, page 15).

The Office Action never indicates that (once all of the proposed modifications to the prior art are made), there would be a region in the resulting product promoting salivation, and a second region providing oral comfort, as claimed. With respect to motivation (1), the statement is insufficient because one is required to have the desire to achieve the desired result, the treatment of xerostomia, before setting out on the modification of the references, which is hindsight. With respect to motivation (2), the Office Action relies on the use of acidulent as a flavor enhancer to make obvious the use of acidulent to promote salivation. Again, it is submitted that this is only accomplished with hindsight.

For the foregoing reasons, applicants submit that the rejections are based on hindsight, with insufficient attention being paid to the confectionery product claimed. Reconsideration is respectfully requested based on the foregoing amendment and these remarks.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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